

WHAT IS CLAIMED IS:

1. A device for inserting hemostatic material through a tissue channel and against the outside wall of a blood vessel of a patient wherein said blood vessel wall has a puncture therein adjacent said tissue channel, comprising

- (a) a charge of hemostatic material,
- (b) a hollow sheath adapted to pass through said tissue channel, said sheath having a cross sectional profile larger than said puncture,
- (c) means for placing said hemostatic material in said hollow sheath, and
- (d) means for advancing said hemostatic material through said sheath to the outside of said vessel wall around said puncture.

2. The device of claim 1 further comprising a tissue dilator, wherein said sheath is adapted to fit over said tissue dilator.

3. The device of claim 2 wherein said dilator is larger in cross section than said tissue channel and wherein said dilator is adapted to be inserted into said channel, thereby to increase the size of said channel.

4. The device of claim 2 wherein said dilator is also the means for advancing said hemostatic material through said sheath.

5. The device of claim 2 wherein said dilator is larger in cross section than said puncture.

6. The device of claim 2 wherein said hemostatic material is made at least primarily of collagen.

7. The device of claim 1, 2, 3, 4, 5 or 6 wherein said charge of hemostatic material is in the form of a plug of loose fibers.

8. The device of claim 1, 2, 3, 4, 5 or 6 wherein said charge of hemostatic material is in the form of a sponge.

9. The device of claim 1, 2, 3, 4, 5 or 6 wherein said charge of hemostatic material is in the form of a plug partially of loose fibers and partially of a more densely packed construction.

10. The device of claim 1, 2, 3, 4, 5 or 6 wherein said charge of hemostatic material is in the form of a plug having a front end and a back end and wherein said front end is covered with a membrane of hemostatic material and wherein the remainder of said plug is in the form of a densely packed material.

11. The device of claim 1, 2, 3, 4, 5 or 6 wherein said charge of hemostatic material is in the form of a balloon made of collagen membrane.

12. The device of claim 1, 2, 3 or 5 wherein said charge of hemostatic material is in the form of a liquid.

13. The device of claim 12 wherein said liquid is comprised of fibrin glue.

14. The device of claim 12 wherein said liquid is comprised of thrombin.

15. The device of claim 1, 2, 3 or 5 wherein said charge of hemostatic material is in the form of a paste.

16. The device of claim 15 wherein said paste is comprised of fibrin glue.

17. The device of claim 15 wherein said paste is comprised of thrombin.

18. A device for use in sealing a puncture in a wall of a blood vessel of a patient where said blood vessel is separated from the skin of the patient by a layer of tissue, where a tissue channel communicates between said puncture and the patient's skin and where a guide wire having proximal and distal ends extends at least from said puncture, through said channel, to the patient's skin, comprising

(a) a tissue dilator having a front portion and a rear portion,

(b) a dilator channel running through said dilator from said front portion to said rear portion, said dilator channel being adapted to receive therein and pass therethrough the proximal end of said guide wire,

(c) an elongated hollow sheath having a distal end and a proximal end, said sheath being adapted to pass over said dilator,

(d) hemostatic material,

(e) means for inserting said hemostatic material into said sheath,

(f) means for advancing said hemostatic material through said sheath, out of the distal end thereof against said vessel wall around said puncture.

19. The device of claim 18 wherein said tissue dilator also acts as said means for advancing said hemostatic material through said sheath.

20. The device of claim 18 further comprising a plug holder to retain therein said hemostatic material prior to its insertion into said sheath.

21. The device of claim 20 wherein said sheath has a lumen running therethrough from said proximal end to said distal end and wherein said hemostatic material is retained within a channel in said plug holder, further comprising means for aligning said sheath lumen with said plug holder channel whereby said hemostatic material can be fed from said plug holder channel into said sheath lumen.

22. The device of claim 20 wherein said sheath has a lumen running therethrough from said proximal end to said distal end, wherein said plug holder has a channel therein which communicates with said sheath lumen and wherein said hemostatic material is retained within said plug holder channel.

23. The device of claim 21 or 22 wherein said means for inserting said hemostatic material into said sheath is comprised of a plug pusher which is adapted to slide within said plug holder channel thereby to push said hemostatic material from within said plug holder into said lumen of said sheath.

24. The device of claim 21 or 22 wherein said means for advancing said hemostatic material through said sheath is comprised of a piston adapted to slide within said lumen of said sheath.

25. The device of claim 18, 21 or 22 wherein said means for inserting said hemostatic material into said sheath is the same means as advances said hemostatic material through said sheath.

26. The device of claim 18, 19, 20 or 21 wherein said hemostatic material is made primarily or entirely of collagen.

27. The device of claim 23 wherein said hemostatic material is made primarily or entirely of collagen.

28. The device of claim 24 wherein said hemostatic material is made primarily or entirely of collagen.

29. The device of claim 28 wherein said hemostatic material is made primarily or entirely of collagen.

30. The device of claim 18, 19, 20, 21 or 22 wherein said hemostatic material is in the form of a plug of loose fibers.

31. The device of claim 18, 19, 20, 21 or 22 wherein said hemostatic material is densely packed.

32. The device of claim 18, 19, 20, 21 or 22 wherein said hemostatic material is in the form of a plug partially of loose fibers and partially of a densely packed or sponge-like construction.

33. The device of claim 18, 19, 20, 21 or 22 wherein said hemostatic material is in the form of a plug having a front end and a back end and wherein said front end is covered with a membrane of hemostatic material and wherein the remainder of said plug is in the form of a densely packed sponge of hemostatic material.

34. The device of claim 18, 19, 21 or 22 wherein said hemostatic material is in the form of a balloon having a collagen membrane.

35. A device for use in sealing a puncture in a wall of a blood vessel of a patient where said blood vessel is separated from the skin of the patient by a layer of tissue, where a tissue channel communicates between said puncture and the patient's skin and where a guide wire having proximal and distal ends extends at least from said puncture, through said tissue channel, to the patient's skin, comprising

(a) a plug of resorbable hemostatic material having a channel passing therethrough, said plug channel being adapted to receive therein in sliding relation said guide wire,

(b) means for passing said plug over said guide wire through said tissue channel to the outside of said wall of said blood vessel,

(c) means for holding said plug against the wall of said blood vessel around said puncture until self sustaining hemostasis has been achieved.

36. The device of claim 35 further comprising a sheath having a lumen therethrough, wherein said lumen is adapted to receive therein and pass therethrough said plug.

37. The device of claim 35 or 36 wherein said plug is made primarily of collagen in the form of a sponge.

38. The device of claim 37 wherein said plug has a collagen membrane on one face thereof.

39. A method for sealing a puncture in a wall of a blood vessel located beneath body tissue of a patient, which tissue intervenes between said vessel and the skin of said patient, comprising the steps of

(a) establishing communication between said vessel puncture and the skin of said patient, by means of a tissue channel through said tissue,

(b) inserting an hemostatic material through said tissue channel,

(c) applying said hemostatic material to the outside of said wall of said vessel on substantially all sides of said vessel puncture until a self-sustaining hemostatic seal has been achieved.

40. The method of claim 39 wherein said hemostatic material is collagen.

41. The method of claim 39 wherein the cross section of said tissue channel is larger than said vessel puncture.

42. The method of claim 39, wherein said blood vessel is an artery and wherein the average blood pressure within said artery is higher than atmospheric pressure.

43. The method of claim 42 wherein before said hemostatic material is applied to the outside of said vessel wall, the blood pressure within said vessel is reduced.

44. The method of claim 43 wherein said reduced pressure is maintained for at least about one minute after said hemostatic material is first applied to said vessel wall.

45. The method of claim 44 further comprising the step, before inserting said hemostatic material through said tissue channel, of enlarging the cross section of said tissue channel so that it is at least about 30% larger than its cross section prior to said enlargement.

46. A method for sealing a puncture in a wall of a blood vessel of a patient where said puncture lies

beneath the surface of the patient's body and where communication exists between said puncture and said surface via a channel through the tissue which intervenes between said surface and said vessel, comprising the steps of

- (a) inserting a charge of hemostatic material into said tissue channel,
- (b) positioning said hemostatic material against the outside of said vessel wall so as to cover said puncture without causing said hemostatic material to pass through said puncture into said vessel,
- (c) holding said hemostatic material against said vessel until a good self-sustaining hemostatic seal has been achieved.

47. The method of claim 46 further comprising the step of enlarging the size of said tissue channel prior to inserting said hemostatic material.

48. The method of claim 46 wherein the normal pressure of the blood in said blood vessel is higher than atmospheric pressure, further comprising the additional step of reducing said blood pressure in the vicinity of said puncture before applying said hemostatic material to said vessel wall.

49. The method of claim 48 further comprising the step of maintaining said reduced blood pressure for less than about five minutes after said hemostatic material is first applied to said vessel wall.

50. The method of claim 48 further comprising the step of reestablishing said normal blood pressure in the vicinity of said puncture before said seal has become self-sustaining.

51. The method of claim 46 further comprising the step of permitting said hemostatic material to expand so as to fill said tissue channel adjacent said vessel thereby to overlap said puncture substantially around its entire periphery.

52. The method of claim 46 wherein said hemostatic material fills substantially the entire cross sectional area of said tissue channel adjacent said vessel.

53. The method of claim 47 wherein said tissue channel is enlarged so that its cross section is at least about 30% larger than its cross sectional area before said enlargement.

54. The method of claim 46, 48, 49, 50, 51, 52 or 53 wherein said hemostatic material is made at least primarily of collagen.

55. A method for sealing a puncture in a wall of a blood vessel of a patient where said puncture lies within the tissue of the patient's body and where communication exists between said puncture and the surface of the patient's body via a channel through said tissue

- (a) passing a sheath of larger cross section than said puncture through said tissue channel,
- (b) inserting hemostatic material into said sheath,
- (c) advancing said hemostatic material through said sheath to the outside of said vessel wall and applying said hemostatic material over said puncture until a self-sustaining hemostatic seal has been achieved.

56. The method of claim 55 wherein said hemostatic material is advanced through said sheath by passing a

pusher piston into said sheath and exerting axial force on said piston.

57. The method of claim 56 wherein said hemostatic material is held against said vessel wall by said piston, further comprising the step of removing said sheath and said piston from said tissue channel after said self-sustaining seal has been achieved.

58. The method of claim 57 wherein said sheath and said piston are withdrawn from said channel as a unit.

59. The method of claim 55 further comprising the step of withdrawing said sheath from said tissue channel before said self-sustaining seal has been achieved.

60. The method of claim 56 wherein said sheath is withdrawn from said channel before withdrawal of said piston.

61. The method of claim 56 wherein said piston is withdrawn from said sheath before said sheath is withdrawn from said channel.

62. The method of claim 55 or 56 further comprising the step of partially withdrawing said sheath from said tissue channel so as to allow all of said hemostatic material to exit from said sheath.

63. The method of claim 62 further comprising the step of allowing said hemostatic material to fill said tissue channel adjacent said puncture so as to overlap said puncture around substantially its entire periphery.

64. The method of claim 55 wherein said vessel is an artery and wherein the average blood pressure in said

artery is higher than atmospheric pressure, further comprising the step of reducing said blood pressure in the region of said puncture before said hemostatic material is advanced to said vessel wall.

65. The method of claim 64 wherein said reduced pressure is maintained for about one minute after said hemostatic material reaches said artery wall.

66. The method of claim 65 further comprising the step of reestablishing said average blood pressure before said seal has become self-sustaining.

67. The method of claim 55, 56, 57, 58, 59, 60, 61, 64, 65 or 66 wherein said hemostatic material is made at least primarily of collagen.

68. The method of claim 62 wherein said hemostatic material is made at least primarily of collagen.

69. The method of claim 63 wherein said hemostatic material is made at least primarily of collagen.

70. The method of claim 39, 46 or 55 wherein said hemostatic material is in the form of a plug of loose fibers.

71. The method of claim 39, 46 or 55 wherein said hemostatic material is in the form of a sponge.

72. The method of claim 39, 46 or 55 wherein said hemostatic material is partially in the form of a sponge and partially in the form of loose fibers.

73. The method of claim 39, 45 or 55 wherein said hemostatic material is in the form of a sponge with a membrane of hemostatic material on one face thereof.

74. The method of claim 39, 46 or 55 wherein said hemostatic material forms the membrane of a balloon, comprising the further step of inflating said balloon so that said membrane covers said puncture.

75. The method of claim 39, 46 or 55 wherein said hemostatic material is in the form of a liquid.

76. The method of claim 75 wherein said liquid is comprised of fibrin glue.

77. The method of claim 76 wherein said liquid is comprised of thrombin.

78. The method of claim 39, 46 or 55 wherein said hemostatic material is in the form of a paste.

79. The method of claim 78 wherein said paste is comprised of fibrin glue.

80. The method of claim 78 wherein said paste is comprised of thrombin.

81. A method for sealing a puncture in a wall of a blood vessel of a patient where said puncture lies beneath the skin of the patient's body and where communication exists between said puncture and the surface of the patient's body via a channel through the tissue which intervenes between said puncture and said surface and wherein a guide wire passes at least from said puncture, through said tissue channel to the surface of the patient's body, comprising the steps of  
(a) passing a sheath of larger cross section than said puncture through said tissue channel to said vessel wall,

- (b) inserting hemostatic material into said sheath,
- (c) advancing said hemostatic material over said guide wire through said sheath to the outside of said vessel wall,
- (d) holding said hemostatic material against the outside of said vessel wall until a self-sustaining hemostatic seal has been achieved.

82. A method for sealing a puncture in a wall of a blood vessel of a patient where said puncture lies beneath the skin of the patient's body and where communication exists between said puncture and the surface of the patient's body via a channel through the patient's tissue comprising the steps of

- (a) passing a sheath through at least a portion of said tissue channel without permitting said sheath to reach said vessel wall,
- (b) inserting a first charge of hemostatic material into said sheath,
- (c) advancing said charge of hemostatic material through said sheath to the outside of said vessel wall,
- (d) applying said hemostatic material over said puncture until a hemostatic seal has been achieved.

83. The method of claim 82 wherein said sheath is of larger cross section than said puncture.

84. The method of claim 82 wherein before said sheath is passed through said tissue channel, a dilator is passed into said tissue channel over a guide wire.

85. The method of claim 82 wherein said hemostatic material is advanced through said sheath by passing a pusher piston into said sheath and exerting axial force on said piston.

86. The method of claim 85 further comprising the step of partially withdrawing said sheath from said tissue channel so as to allow all of said first charge of hemostatic material to exit from said sheath.

87. The method of claim 86 further comprising the step of allowing said hemostatic material to fill said tissue channel adjacent said puncture so as to overlap said puncture around substantially its entire periphery.

88. The method of claim 87 further comprising the step of inserting a second charge of hemostatic material with said sheath, advancing said second charge through said sheath until it abuts said first charge of hemostatic material.

89. The method of claim 88 wherein said second hemostatic charge is advanced through said sheath by passing a pusher piston into said sheath and exerting axial force on said piston.

90. The method of claim 88 further comprising the steps of

- maintaining pressure on said first charge through said second charge,
- maintaining pressure on said second charge,
- withdrawing said sheath until all of second charge exits therefrom.

91. The method of claim 88 further comprising the step of further withdrawing said sheath from said tissue channel so as to allow all of said second charge of hemostatic material to exit from said sheath.

92. The method of claim 91 further comprising the step of allowing said second charge of hemostatic material to fill substantially all of the remainder of said tissue channel.

93. The method of claim 92 wherein said vessel is an artery and wherein the average blood pressure in said artery is higher than atmospheric pressure, further comprising the step of reducing said blood pressure in the region of said puncture before said first charge of hemostatic material is advanced to said vessel wall.

94. The method of claim 93 wherein said reduced pressure is maintained until self-sustaining hemostasis has been achieved.

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